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UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MARC MEHRZAD JALISI, DAVID M. ANDERSON,
WAYNE E. CORNISH, NANCY A. NICOTRA,
and MARK T. RICHARDSON

Appeal 2009-000802
Application 09/470,874
Technology Center 3700

Decided:¹ June 3, 2009

Before DEMETRA J. MILLS, LORA M. GREEN, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a heat treated elongate member. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

Statement of the Case

Background

“Conventional guidewires for angioplasty and other vascular procedures usually comprise an elongated core member with one or more tapered sections near the distal end thereof and a flexible body such as a helical coil disposed about the distal portion of the core member” (Spec. 1, ll. 14-17). According to the Specification, a “shapeable member, which may be the distal extremity of the core member or a separate shaping ribbon which is secured to the distal extremity of the core member extends through the flexible body and is secured to a rounded tip at the distal end of the flexible body” (Spec. 1, l. 17 to 2, l. 3).

The Claims

Claims 1-15, 17, 19-27, and 29 are on appeal. We will focus on claims 1, 8, 20, and 26, which are representative and read as follows:

1. A heat-treated elongate member, comprising:
 - a composite elongate core;
 - the composite elongate core including an inner core formed of a precipitation hardened material and a layer formed of a superelastic material; and
 - a second layer concentrically arranged about the layer formed of the superelastic material;
 - wherein the layer is arranged concentrically about the inner core.

8. A heat-treated elongate member, comprising:
 - a composite elongate core;
 - the composite elongate core including an inner core formed of a precipitation hardened material concentrically surrounded by a first layer formed of a superelastic material and having a proximal section and distal section;
 - a flexible body distinct from the first layer at least partially overlying the distal section; and
 - wherein the precipitation hardenable material comprises at least two materials selected from the group consisting of nickel, cobalt, molybdenum, chromium, tungsten, and iron.
20. The elongate member [wherein the inner core and the first layer are independently formed and wherein the first layer is formed from superelastic NITINOL and]
 - wherein the composite elongate core further includes a second layer disposed at least in part concentrically about the first layer and formed from a material similar to the inner core material.
26. A guide wire, comprising:
 - a composite elongate core;
 - the composite elongate core including an inner core formed of a precipitation hardened material concentrically surrounded by a layer formed of a superelastic material and having a proximal section and distal section;
 - a flexible coil disposed at a distal end of the distal section;
 - wherein the precipitation hardened material and superelastic material extend from the proximal section to at least through a part of a length of the flexible coil.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Thome et al.	US 5,776,080	Jul. 7, 1998
Fagan et al.	WO 96/25969	Aug. 29, 1996

The issue

The Examiner rejected claims 1-15, 17, 19-27, and 29 under 35 U.S.C. § 103(a) as being obvious over Thome and Fagan (Ans. 3).

The Examiner finds that

Thome teaches a medical guidewire having a heat-treated elongate member comprising a composite core (150), the composite core section including an inner core (154) formed of Hiperc (Col 13 line 50) wire, and a layer formed of a superelastic material (178, Nitinol), and a second layer concentrically arranged about the layer formed of superelastic material (176), wherein the layer is arranged about the inner core . . . Thome does not teach that the inner core is formed of a precipitation hardened material. Fagan teaches a precipitation hardened material (stainless steel) for use in a medical guide wire (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the precipitation hardened material of Fagan with the guide wire of Thome as an alternate material

(Ans. 3).

Appellants contend that the “Thome et al. patent does not teach [the claimed] structure since the metallic layer 178 forms the **outermost surface** of the Thome et al. device and thus, Thome et al. does not disclose or even contemplate a second layer concentrically arranged about a layer formed of superelastic material” (App. Br. 6). Appellants also contend that the

“Examiner has not demonstrated . . . that the layer of resin 176 at least partially **overlays** a first layer formed of a superelastic material as is recited in the claims” (App. Br. 7).

In view of these conflicting positions, we frame the obviousness issues before us as follows:

- (i) Did the Examiner err in finding that Thome and Fagan teach “a second layer concentrically arranged about the layer formed of the superelastic material” as required by claim 1?
- (ii) Did the Examiner err in finding that Thome and Fagan teach a “composite elongate core including an inner core formed of a precipitation hardened material concentrically surrounded by a first layer formed of a superelastic material and having a proximal section and distal section” as required by claim 8?

Findings of Fact (FF)

1. The Specification teaches that “the composite elongate core member further includes a second layer portion disposed at least in part about the first layer portion and formed of a material similar to the inner core element material” (Spec. 7, ll. 2-5).

2. Figure 2 of the Specification is reproduced below:

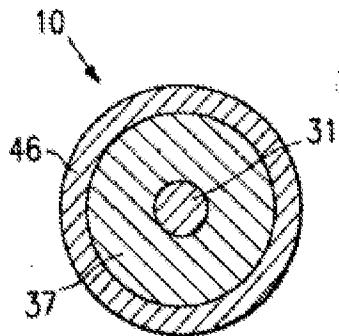


FIG. 2

"FIG. 2 is a transverse cross sectional view of the guidewire" (Spec. 8, l. 7).

3. The Specification teaches that the elongate core member 11 has an inner core element 31 formed from a precipitation hardenable material, a first layer portion 37 formed from a superelastic material disposed on an outer surface 43 of the inner core element 31, and a second layer portion 46 formed from precipitation hardenable material disposed on an outer surface 52 of the first layer portion 37.

(Spec. 9, ll. 7-12.)

4. Thome teaches a guide wire in figure 25, reproduced below:

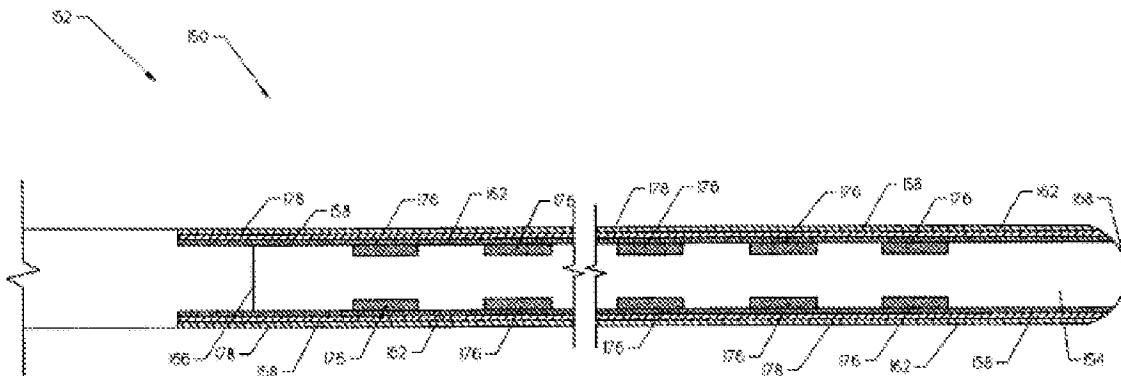


FIG. 25

“**FIG. 25** is a detailed sectional view of an operative segment of a guide wire” (Thome, col. 5, ll. 15-16).

5. Thome teaches a guidewire with a composite elongate core where “[c]ore **154** is formed of a highly paramagnetic material relative to the rest of operative segment **150**” (Thome, col. 13, ll. 46-47; Fig. 25). Thome also teaches an alternative where “core **154** is formed of solid stainless steel, having a uniform outside diameter” (Thome, col. 16, ll. 32-33).

6. Thome teaches that “a thin walled tubular member **158** is placed over the core **154**. In a preferred embodiment, the thin walled tubular member **158** is formed of a **304** stainless steel hypotube, which is secured to the core **154** by an adhesive layer **162**” (Thome, col. 16, ll. 49-52).

7. Thome teaches that the “thin walled tubular member **158** is coated with a metallic layer **178**” (Thome, col. 16, ll. 52-53).

8. Thome teaches that “the metallic layer **178** is formed of a material having superelastic properties, such as Nitinol” (Thome, col. 16, ll. 54-56).

9. Thome teaches that “[n]otched segments **160** are filled with a material **176**, such as epoxy resin” (Thome, col. 17, ll. 10-11).

10. Thome teaches that “operative segment **150** includes multiple layers of strands **182** tightly wrapped around core **154**. In a preferred embodiment, the strands **182** are formed of stainless steel ribbons or composite fibers filled with epoxy ribbon” (Thome, col. 17, ll. 14-17).

11. Figure 26 of Thome is reproduced below:

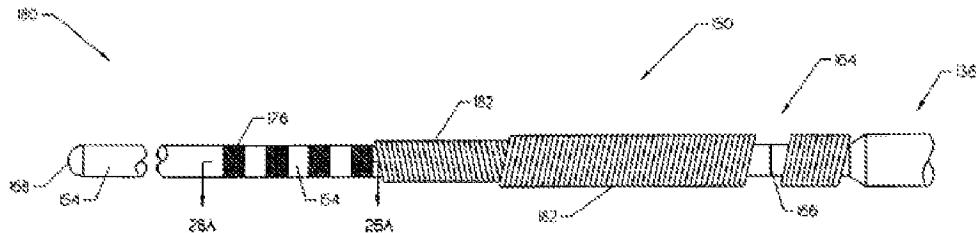


FIG. 26

“FIG. 26 is a fragmented perspective view of an operative segment of a guide wire” (Thome, col. 5, ll. 18-19).

12. Fagan teaches that the “guidewire shaft may be formed from a precipitation hardenable alloy such as an alloy of nickel, cobalt, molybdenum and chromium (MP35N and Elgiloy), 455PH stainless steel or stainless steel alloy 1RK91” (Fagan, abstract).

13. The Examiner finds that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to use the precipitation hardened material of Fagan with the guide wire of Thome as an alternate material” (Ans. 3).

Principles of Law

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that “the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of

the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 416. “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 417.

Moreover, an “[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious.” *In re Fout*, 675 F.2d 297, 301 (CCPA 1982). As noted by the Court in *KSR*, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” 550 U.S. at 421.

Claim terms are interpreted using the broadest reasonable interpretation in light of the Specification. *See, e.g., In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) (“[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.”). *Also see In re Morris*, 127 F.3d 1048, 1054-56 (Fed. Cir. 1997). (“Absent an express definition in their specification, the fact that appellants can point to definitions or usages that conform to their interpretation does not make the PTO's definition unreasonable when the PTO can point to other sources that support its interpretation.”)

Analysis

Claim 1

Whether the combination of Thome and Fagan render claim 1 obvious depends upon the interpretation of “a second layer concentrically arranged about the layer” (*see Claim 1*). The Examiner finds that the “term ‘arranged about’ does not have to mean outside or exterior” (Ans. 5).

We disagree with the Examiner’s understanding of the term “arranged about” in this instance. The Specification only teaches the situation where the second layer is placed outside the first layer (FF 1-3). The broadest reasonable interpretation consistent with the Specification of “a second layer concentrically arranged about the layer formed of the superelastic material” is that the layer is on the outside of the first layer.

However, even relying solely upon the language of the claim, the phraseology used requires an order. The claim requires an inner core, which being “inner” is necessarily surrounded by the first layer of a superelastic material (Claim 1). The claim then requires a “second layer” (Claim 1). The broadest reasonable interpretation of a “second layer” that is “arranged about” the first layer, is that the second layer is exterior to the first layer. If the “second layer” was interior to the first layer, it would necessarily be termed the first layer, and not the second layer.

We therefore agree with Appellants that the “layer of resin 176 does not meet the claim language of being **arranged about** the superelastic layer 178. The Fagan reference does not disclosed [sic] the claimed structure” (App. Br. 6).

Claims 8, 26, and 27

Thome teaches a composite elongate core with an inner core surrounded by a layer of superelastic material where the layer of resin 176 is a flexible body which partially overlies the composite elongate core (FF 4-9). Fagan teaches the use of precipitation hardened material comprising material such as nickel, cobalt, and molybdenum (FF 12). The Examiner finds that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to use the precipitation hardened material of Fagan with the guide wire of Thome as an alternate material” (Ans. 3; FF 13). *See KSR*, 550 U.S. at 416 (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”)

Claims 8, 26, and 27 do not expressly require the same order as claim 1, since the “flexible body distinct from the first layer” (Claim 8), the “flexible coil disposed at a distal end of the distal section” (Claim 26) and the “flexible body disposed at a distal end” (Claim 27) are not identified as second layers unlike the “second layer” claim 1.

Therefore, in analyzing claim 8, the issue is whether the phrase “having a proximal section and distal section” necessarily refers to the “first layer formed of a superelastic material” or whether the phrase can also be interpreted to modify the “composite elongate core.”

Under the broadest reasonable interpretation rubric, we find that the Examiner has reasonably interpreted the phrase “having a proximal section and distal section” in claim 8 as broadly applying to either the composite elongate core *or* the first layer formed of a superelastic material. *See In re*

Zletz, 893 F.2d 319, 321-322 (Fed. Cir. 1989) (“[D]uring patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.”).

Appellants had, and still have, opportunities to clarify this claim language to limit which element in claims 8, 26, and 27 is intended by “having a proximal section and a distal section” (*see* Claim 8).

We are not persuaded by Appellants’ argument that the “Examiner has not demonstrated, however, that the layer of resin 176 at least partially **overlays** a first layer formed of a superelastic material as is recited in the claims” (App. Br. 7). Since we agree with the Examiner that the “flexible” layer may overlay either the core or the first layer, layer 176 satisfies this limitation since layer 176 is clearly shown by Thome to overlay the core.

We also are not convinced by Appellants’ argument regarding claims 26 and 27 that “multi-layered strands 182 are described in Thome . . . as the **proximal most portion** of guide wire 36 . . . Increased pushability and torqueability are usually associated with components located at the proximal, not the distal portion of a guide wire” (App. Br. 8).

In analyzing the meanings of the claim terms “proximal” and “distal,” we begin by reviewing the language of claims 26 and 27, which simply require “a proximal section and distal section” (Claim 26). Claims 26 and 27 do not identify or require a particular end of the elongate member to function as the proximal end or as the distal end. Consequently, the Examiner

reasonably interprets the strands 182 as placed at the distal end, satisfying the requirements of claims 26 and 27 (FF 10-11).

Appellants point to no limitation in claim 26 and 27 which imposes a requirement or identifies which end of the elongate member is the “proximal end” and which is the “distal end.” Here, we decline to read an orientation limitation regarding distal and proximal into claims 26 and 27 that is not currently required by the plain language of the claim. “[L]imitations are not to be read into the claims from the specification.” *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) (citing *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989)).

Claims 20 and 21

Appellants contend that “the cited art does not teach the subject matter recited in at least dependent claims 20 and 21 which require a second layer disposed at least in part about the first layer (formed form superelastic material), the second layer formed from material similar to the core element material” (App. Br. 7).

For the reasons given in analyzing claim 1, we agree with Appellants that Thome and Fagan do not teach a “second layer” as required by claims 20 and 21.

Conclusions of Law

- (i) The Examiner erred in finding that Thome and Fagan teach “a second layer concentrically arranged about the layer formed of the superelastic material” as required by claims 1, 20, and 21?
- (ii) The Examiner did not err in finding that Thome and Fagan teach a “composite elongate core including an inner core formed of a precipitation

hardened material concentrically surrounded by a first layer formed of a superelastic material and having a proximal section and distal section” as required by claim 8.

SUMMARY

In summary, we reverse the rejection of claims 1-7, 9-12, 20, 21, and 29 under 35 U.S.C. § 103(a) as obvious over Thome and Fagan.

We affirm rejection of claims 8, 26, and 27 under 35 U.S.C. § 103(a) as obvious over Thome and Fagan. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 13-15, 17, 19, and 22-25 as these claims were not argued separately.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED-IN-PART

cdc

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